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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,962	02/02/2004	Darin G. Schaeffer	10703/042	9118
7590	05/04/2005		EXAMINER	
BRINKS HOFER GILSON & LIONE ONE INDIANA SQUARE, SUITE 1600 INDIANAPOLIS, IN 46204			ALI, SHUMAYA B	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/769,962	SCHAEFFER ET AL.	
	Examiner Shumaya B. Ali	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 February 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11 and 22-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 12-21 is/are allowed.
- 6) Claim(s) 1-9, 22-28, 30 and 31 is/are rejected.
- 7) Claim(s) 5, 10, 11 and 29 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input checked="" type="checkbox"/> Other: <u>detailed action</u> . |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1,2,8,9,22, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Hazard US

Patent 5,058,580

2. **As to claim 1, Hazard discloses** a tracheotomy tube (see fig.1 reference object 10) comprising: a hollow tubular body (fig.1 reference object 12) having a proximal end portion (fig.1 reference object 16, col.4 lines 10-11), a distal end portion (fig.1 reference object 14, col.4 lines 8-10) and a curved portion (col.4 lines 17-19) intermediate said proximal and distal end portions (fig.1 seems to depict a curved portion between the distal and proximal end of the tube); and a flange (fig.1 reference object 26) situated at said proximal end portion (col.4 lines 43-45), said flange being capable of radial extension from said tube (col.4 lines 49-50), and being manipulatable to selectively prevent said radial extension (the flange have two end extensions, see fig.1 near reference object 27 that are capable of preventing radial extension).

3. **As to claim 2, Hazard discloses** the tracheotomy tube of claim 1, wherein said flange is selectively attachable (col.4 lines 48-50) to said proximal end portion to provide said radial extension and detachable (by removing a strap holding the flange to the tube, see col.4 lines 45-46) from said proximal end portion when said radial extension is to be prevented.

4. **As to claim 8, Hazard discloses** the tracheotomy tube of claim 1, further comprising a removable inner cannula (fig.7 reference object 10) insertable in said hollow tubular body.

5. **As to claim 9, Hazard discloses** the tracheotomy tube of claim 1, wherein said hollow tubular body includes an inflatable cuff (fig.1 reference object 18) surrounding a part of said distal end portion (col.4 lines 32-35), said tracheotomy tube further comprising an inflation line (fig.1 reference object 22) connecting said cuff to a source (fig.1 reference object 20, col.4 lines 38-41) of an inflation fluid.

6.

7. **As to claim 22, Hazard discloses** a device for percutaneous insertion into the trachea of a patient, comprising: a tracheotomy tube (see fig.1 reference object 10) having a longitudinal passageway (col.3 lines 2-4) there through, said tracheotomy tube having a distal end (fig.1 reference object 14) portion percutaneously insertable into said trachea and a proximal end (fig.1 reference object 16) portion exterior to the trachea when said distal end portion is inserted; said tracheotomy tube further having a radially extending flange (fig.1 reference object 26) attachable to said proximal end portion of the tracheotomy tube after said distal end portion has been inserted into the trachea (see fig.6); a dilator (fig.4 reference object 34) positionable within said longitudinal passageway of said tracheotomy tube (col.3 lines 5-18) for dilating an opening in said trachea for insertion of said tracheotomy tube; and a locking assembly (fig.1 reference object 37, col.5 lines 20-25) for locking the tracheotomy tube to the dilator during insertion of said tracheotomy tube into the trachea.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hazard US Patent 5,058,580

9. **As to claim 3, Hazard does not disclose the tracheotomy tube of claim 2, wherein said flange is attachable to said tube by a snap-fit. However, applicant has not established criticalities regarding the type of fit used in the invention. Therefore, Hazard's disclosure of a flange with a strap attachment is considered an equivalent structure capable of securing the flange to the tube (col.4 lines 43-50).**

Claims 4,6,7,23-28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hazard US Patent 5,058,580 in view of Roy US Patent 6,135,110

10. **As to claim 4, Hazard discloses the tracheotomy tube of claim 3, and wherein said flange includes a cut-away portion, said cut-away portion (fig.1 recessed region of 26 where a tube is situated) and said groove being cooperatively sized and shaped to mate when said flange is attached to said tube, however does not disclose wherein said hollow tubular body includes a collar at its proximal end, said collar having a groove, As to claim 4, Roy teaches a tracheotomy tube with a snap ring that is rotably mounted about a proximal end of the tube (col.2 lines 20-21) that are meant to mate with tabs for guiding the movement of tabs (col.4 lines 38-39). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the tube of Hazard in view of Roy in order to provide a collar at the proximal end of the tube which will be capable of guiding and preventing movements inside the tube.**

11. **As to claim 6, Hazard does not disclose the tracheotomy tube of claim 4, wherein said collar is integral with the hollow tubular body. . As to claim 6, Roy teaches a tracheotomy tube with a collar rotatably mounted ("integral") about an end of the tube (see col.4 lines 3-5) contacting tab members for guiding the movement of the tabs relative to the collar, and the collar has two stops to prevent any further movement of a tab. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the tube assembly of Hazard in view of Roy in order to provide the assembly with a collar associated with the securement member for the purposes of preventing or guiding movement of the tube.**

12. **As to claim 7, Hazard discloses the tracheotomy tube of claim 4, wherein said collar includes one or more barbs for attaching the collar to said hollow tubular body. However, applicant has not established criticalities regarding the attachment means including one or more barbs to be used in the invention. Therefore, Hazard's disclosure of a flange with a strap attachment means is considered an equivalent structure capable of securing the flange to the tube (col.4 lines 43-50).**

13. **As to claim 23, Hazard discloses the device of claim 22, wherein said locking assembly comprises a securement member (fig.1 reference object 37) associated with the dilator, however does not disclose said securement member engageable with a complementary member on said tracheotomy tube. As to claim 23, Roy teaches a tracheotomy tube with a collar contacting tab members for guiding the movement of the tabs relative to the collar, and the collar has two stops to prevent any further movement of a tab. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the tube assembly of Hazard in view of Roy in order to provide the assembly with a collar for the purposes of preventing or guiding movement of the tube.**

14. **As to claim 24, Hazard does not disclose** the device of claim 23, wherein said locking assembly further comprises a stop member disposed on an outer surface of said dilator, said stop member engaged with said dilator such that substantial axial movement of said stop member along said dilator is prevented when an axial force is applied to said stop member, said stop member positioned on said outer surface and engageable with said securement member and said complementary member for preventing excess penetration of the tracheotomy tube into the trachea. **As to claim 24, Roy teaches a tracheotomy tube with a collar contacting tab members for guiding the movement of the tabs relative to the collar, and the collar has two stops to prevent any further movement of a tab.** Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the tube assembly of Hazard in view of Roy in order to provide the assembly with a collar associated with the securement member for the purposes of preventing or guiding movement of the tube.

15. **As to claim 25, Hazard discloses** the device of claim 24, wherein said stop member comprises an annular ring (fig.5 seems to depict reference object 37 as a ring like structure) integral with said dilator.

16. **As to claim 26, Hazard discloses** the device of claim 24; wherein said stop member comprises an annular ring fitted on the outer surface (the ring is on the proximal portion of the dilator, col.5 lines 19-20) of said dilator.

17. **As to claim 27, Hazard does not disclose** the device of claim 24, wherein said complementary member comprises a collar integral with said tracheotomy tube. **As to claim 27, Roy teaches a tracheotomy tube with a collar rotatably mounted ("integral") about an end of the tube (see col.4 lines 3-5) contacting tab members for guiding the movement of the tabs relative to the collar, and the collar has two stops to prevent any further movement of a tab.** Therefore, it would have been

obvious to one of ordinary skills in the art at the time the invention was made to modify the tube assembly of Hazard in view of Roy in order to provide the assembly with a collar associated with the securement member for the purposes of preventing or guiding movement of the tube.

18. As to claim 28, Hazard discloses he device of claim 24, wherein said complementary member comprises a collar fitted on an exterior surface of said tracheotomy tube. As to claim 28, Roy teaches a tracheotomy tube with a collar rotatably mounted ("integral") about an end of the tube (fig.1a depicts a collar mounted on a tube, see col.4 lines 3-5) contacting tab members for guiding the movement of the tabs relative to the collar, and the collar has two stops to prevent any further movement of a tab. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the tube assembly of Hazard in view of Roy in order to provide the assembly with a collar associated with the securement member for the purposes of preventing or guiding movement of the tube.

Drawings

19. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, in the claim 5, "receptacle" and 29, "a cap" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

20. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and

where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

21. Claims 5 and 29 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims recite limitation "receptacle" and "a cap" which is not distinctly pointed out in the drawings. It is unclear what the applicant disclosed to be "receptacle" and "a cap". Therefore, claims 5 and 29 are not considered for the examination purposes.

Allowable Subject Matter

22. **Claims 12-21 are allowed.** As to claim 12, the prior art of record does not teach nor render obvious the overall claimed combination of a dilator used with a tracheotomy tube where the proximal end of the dilator has a larger-diameter stepped portion to limit axial movement of the dilator through the tube. Therefore, the invention defined in claim 12 is novel.

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23. **Claims 10 and 11** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

24. The prior art made of record on form PTO-892 and not relied upon discloses tracheotomy tube assembly.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shumaya B. Ali** whose telephone number is **571-272-6088**. The examiner can normally be reached on M-F 8:30 am-4:30 pm.

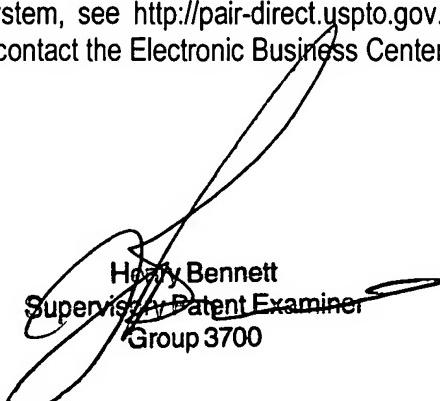
26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Henry Bennett** can be reached on **571-272-4791**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shumaya B. Ali
Examiner
Art Unit 3743

5/2/05



Henry Bennett
Supervisory Patent Examiner
Group 3700